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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,070	01/29/2002	Thomas C. Evans	NEB-177-PUS	4532
28986	7590	03/24/2006	EXAMINER	
HARRIET M. STRIMPEL; NEW ENGLAND BIOLABS, INC. 240 COUNTY ROAD IPSWICH, MA 01938-2723			SCHNIZER, HOLLY G	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,070	EVANS ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 19 is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 13-18 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

The Amendment after final Rejection has been entered. Claims 1-19 are pending.

Withdrawal of Final Rejection

The rejections have been overcome as discussed below. However, upon review of the art of record, a new rejection has been made. Therefore, the finality of the previous Office Action is withdrawn.

Claim Objections--Withdrawn

The objection of Claim 14 for the recitation of "wherein said the target polypeptide" in lines 1-2 of the claim is withdrawn in light of the amendment. The objection of Claim 17 is withdrawn in light of the Amendment and Response filed 2/24/06.

Rejections Withdrawn

The rejection of Claims 12, 14, and 16 under 35 U.S.C. 102(a) as being anticipated by Scott et al. (ref. CN of IDS) is withdrawn in light of the Declaration under 37 CFR 1.131 by Dr. Xu.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 13-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Evans et al. (J. Biol. Chem. (June 25, 1999) 274(26): 18359-18363; ref. BG of IDS filed 10/15/01).

Evans et al. teaches a method of making a cyclic polypeptide by fusing the C-terminal portion of a split intein (Ssp mini-intein) to the N-terminus of a target polypeptide (BBP, RGD, or CDR-H3/C2) and fusing the N-terminal portion of a split intein (Mxe GyrA intein) to the C-terminus of the target to produce a fused polypeptide, fusing an affinity binding domain (a chitin binding domain) to the fused polypeptide, immobilizing the fused product on an affinity based solid support (chitin column), incubating the immobilized precursor under conditions that favor formation of the cyclic polypeptide, and eluting the cyclic polypeptide from the solid support (see p. 18360). BBP, RGD, and CDR-H3/C2 are cyclic peptides. The inteins used in the method of Evans et al. appear to be artificially split inteins. An artificially split intein and a naturally split intein have identical function and could not be distinguished from each other except by knowing how they were made. Thus, Claim 16 is rejected because an

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artificially split intein is not patentably distinguishable from a naturally split intein. Thus, Evans et al. meets the limitations of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-11, and 14-18 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claimed methods are incomplete because they do not have a method of eluting the polypeptides from the column. Incorporation of the limitation of Claim 2 into Claim 1 and Claim 13 into Claim 11 would overcome this rejection.

Claim 13 recites the limitation "said solid support" in line 2. There is insufficient antecedent basis for this limitation in the claim with regard to its dependency from Claim 12 (Claim 12 does not involve a solid support). The examiner notes that the claim is indicated as being original. However, the dependency from Claim 12 appears to have been added (thus the claim is amended). Correction is required.

Claim Objections

Claim 17 is objected to for the recitation of "claims 11". Correction to "claim 11" would overcome this objection.

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Claim 2 is objected to for being dependent from a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

Related Art

US 6,849,428 includes Evans and Xu (the inventors of the present application) as inventors and has the same assignee. Claims 11 and 15 of the '428 patent are closely related to Claim 11 of the present application except that the '428 patent does not claim or disclose that the target protein is fused to an affinity binding domain or that a split intein is used in the method of cyclization. A review of the art did not reveal a teaching or suggestion of using split inteins in a process of cyclization in a method like that presently claimed. Thus, it appears that it would not have been obvious to modify the method of Claim 15 of the '428 patent to use a split intein as is required by the present claims.

Conclusions

Claims 1, 3-11 and 13-18 are rejected. Claims 2, 12 and 19 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday-Thursday from 10 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Holly Schnizer', is positioned above the printed name.

Holly Schnizer
March 9, 2006

HOLLY G. SCHNIZER, PH.D.
PATENT EXAMINER